

**REMARKS**

Claims 1, 3-18 and 20-22 are pending in the application. Claims 3 and 10-16 have been previously withdrawn by the Examiner, as being drawn to non-elected inventions or species. Claims 1, 4-9, and 17, 18 and 20-22 are presently under consideration. Claims 8 and 21 have been amended. Support for the amendment to claim 8 may be found at least at paragraph [0056] of the specification. Support for the amendment to claim 21 may be found throughout the specification and claims as originally filed. Therefore, no new matter has been introduced.

The claim amendments should not be construed to be an acquiescence to any of the claim rejections. Rather, the amendments are being made solely to claim more clearly the invention and to expedite the prosecution of the instant application. Applicants reserve the right to prosecute further the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 U.S.C. § 120.

Favorable reconsideration is respectfully requested in view of the forgoing amendments and the following remarks.

***Rejection Under 35 U.S.C. § 112, Second Paragraph: Indefiniteness***

The Examiner has rejected claim 21 under 35 U.S.C. § 112, for being indefinite, due to its dependence upon a cancelled claim. Applicants have corrected the typographical error in claim 21, to make it dependent upon claim 1. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

***Rejection Under 35 U.S.C. § 102(e)***

Claims 1, 4-9, and 17-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Yoshinaga *et al.* (U.S. Patent No. 7,482,325). The Examiner contends that Yoshinaga *et al.* “teach and claim a method of inhibiting T cell proliferation in a patient by administering to the patient a soluble fusion protein comprising B7RP-2 (see entire document, in particular e.g. claims 1-8), wherein the patient has an autoimmune disease (e.g. claim 2)”. Applicants respectfully traverse the rejection.

As the Examiner is aware, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051,

1053 (Fed. Cir. 1987). Applicants respectfully submit that Yoshinaga *et al.* does not meet this standard.

Yoshinaga *et al.* claims a fusion polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:2 fused in-frame to the Fc portion of human IgG1, B7RP-2-Fc (*See* page 17, lines 30-35 and page 59, lines 30-33). The Examiner contends that the B7RP-2 polypeptide of SEQ ID NO: 2 taught by Yoshinaga *et al.* is identical in sequence to the instant SEQ ID NO: 7. Applicants respectfully disagree. A global sequence alignment of SEQ ID NO:2 of Yoshinaga *et al.* to SEQ ID NO:7 of the instant application, indicates a 35% identity (submitted herewith as Appendix A). Applicants thus submit that Yoshinaga *et al.* describes and claims a fusion polypeptide having a sequence that is substantially different from SEQ ID NO:7 of the instant application.

Furthermore, analysis of the specification shows that Yoshinaga *et al.* states that the claimed B7RP-2-Fc “inhibited T-cell proliferation” (*See* page 59, lines 45-46 and Example 4). Therefore, a method of “inhibiting T-cell proliferation” or “downregulating an immune response” in a patient, as recited in claims 1 and 3 of Yoshinaga *et al.* would clearly involve the administration of a fusion polypeptide comprising SEQ ID NO:2 fused to Fc, not the B7-H3 polypeptide of the instant claims.

Moreover, in Example 6, Yoshinaga *et al.* investigates the role of B7RP-2 (not B7RP-2 fused to an Fc) in experimental autoimmune encephalomyelitis (EAE). Yoshinaga *et al.* states that “the average day of disease onset (the first day when the clinical score was higher than 1) was earlier in B7RP-2 -/- mice (day 16.1; n=16) than in B7RP-2 +/+ mice (day 18.4; n=14)” supporting the conclusion that B7RP-2 negatively regulates Th-1 driven immune responses (*See* page 61, lines 25-56). However, Yoshinaga *et al.* states that “despite the earlier onset, B7RP -/- mice had the same clinical scores as B7RP-2 +/+ mice by the late stages of the disease”. In fact, the “rates of disease incidence or mortality were equivalent between B7RP-2 -/- and B7RP-2 +/+ mice” (emphasis added). Therefore, according to Yoshinaga *et al.*, B7RP-2 does not treat or ameliorate an autoimmune disease. Applicants therefore submit that Yoshinaga *et al.* do not teach or suggest the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

**CONCLUSION**

In view of the above amendments and remarks, Applicants believe that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617)832-1000. The Director is hereby authorized to charge any deficiency that should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our **Deposit Account No. 06-1448**, under Ref. No. **WYS-005.01**.

Respectfully submitted,  
Foley Hoag LLP

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***Customer No: 58571***

Patent Department

Foley Hoag, LLP

155 Seaport Blvd.

Boston, MA 02210-2600

By: /DeAnn F. Smith/  
DeAnn F. Smith, Esq  
Reg. No. 36,683  
Attorney for Applicants